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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Judith Edmonds Starkey

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EXAMINER

PORTER, RACHEL L

ART UNIT

PAPER NUMBER

3626

MAIL DATE

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06/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/930,668	Applicant(s) STARKEY ET AL.	
	Examiner RACHEL L. PORTER	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendments filed 6/12/08. Claims 1-30 are pending.

Specification

2. The objection to the abstract of the disclosure is hereby withdrawn due to the amendment filed 6/12/08.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a §101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). If

neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and should be rejected as being directed to nonstatutory subject matter.

Exemplary claims 1, 17, and 22 fail to reference any other statutory subject matter (e.g. apparatus, article of manufacture) which is tied into the recited process. It is noted that the claims have been amended to recite the method is "computer-implemented" in the preamble. However, such a recitation is nominal and does not shed light on how such subject matter is incorporated into the step of the recited method. The respective dependent claims fail to correct the shortcomings of the present claim, and therefore are also rejected.

Furthermore, the requirements of 35 U.S.C. 101 are met when "the practical application of the abstract idea produces a useful, concrete, and tangible result" (*State Street Bank & Trust Co. vs. Signature Financial Group, Inc.*, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998)). In general, a method of applying for benefits is conceptually useful for seeking funds or assistance. However, the claims, as presently recited, do not appear to have a concrete result. In particular, it is unclear whether a method of "identifying applying of benefits for a patient" as recited in claims 1-30 can be repeatable and predictable (and thus, concrete), since it appears that the determinations and comparisons are subject to human interaction and not a function of the claimed invention. In other words, exemplary claims 1, 17, and 22 recite conditions such as "making an initial determination based on the initial information," "if it is likely that benefits can be obtained" and "if it is unlikely that benefits can be obtained."

However, the claim provides no objective guidance or limitations to clarify how the determination of eligibility is made, or to clarify which steps will be performed and which results will occur each time the method is performed.

In light of the above, it is respectfully submitted that the claimed invention, although useful, does not have a tangible and concrete result, and thus fails to recite the practical application of an abstract idea to satisfy the requirements of 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-6, 9-12, are rejected under 35 U.S.C. 103(a) as being unpatentable over "Indicare™- On-line Patient Assistance Program Website Users Manual." (referred to hereinafter as Indicare) in view of Pritchard (US 4,491,725) and in further view of Hickey (USUS 2002/0107849A1)

[claim 1] Indicare discloses a method for identifying and applying for benefits for a patient comprising:

- obtaining initial patient information (i.e. application/enrollment forms (page 3, 7-10; 15-16).

- based upon initial patient information, making an initial determination as to whether it is likely that the benefits can be obtained (pg. 12, step 7)
- if the initial determination is that benefits are likely to be obtained, obtaining additional patient information, (page 17—indicates whether pharmaceutical company is likely to decline/ require additional information.)

Indicare discloses receiving patient information for a benefit program, but does not expressly disclose the steps of receiving a referral from a medical facility for a patient” and rejecting the referral if the initial determination is that it is unlikely that benefits will be obtained.

Pritchard discloses a method further comprising receiving a referral from a medical facility for a patient and rejecting the referral if the initial determination is that it is unlikely that benefits will be obtained. (col. 4, lines 30-42; 65-col. 5, line 3; col. 7, lines 7-36—likely or unlikely to receive benefits). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Indicare with the teaching of Pritchard to provide an indication of whether or not benefits will be received. As suggested by Pritchard, one would have been motivated to include these features to minimize the hardship to patients by reducing the likelihood that they will have to pay full service fees, while not shifting the burden to healthcare providers. (col. 2, lines 15-25)

Claim 1 has been amended to further recite:

“if the second determination is that it is likely that benefits can be obtained, then receiving additional information for the patient to complete an application the assistance

program and at least one of submitting the completed application to the assistance program and providing a copy of the completed application for submission to the assistance program.”

Indicare and Pritchard disclose the limitations of claim 1, as explained above but do not expressly disclose “if the second determination is that it is likely that benefits can be obtained, then receiving additional information for the patient to complete an application the assistance program and at least one of submitting the completed application to the assistance program and providing a copy of the completed application for submission to the assistance program.”

However, it is well-known in the art to applicants or potential beneficiaries provide additional information as they become more likely to receive the desired benefit. For example Hickey discloses a method wherein a user provides initial information, and if determination is that it is likely that benefits can be obtained, then receiving additional information for the user to complete an application the assistance program and at least one of submitting the completed application to the assistance program and providing a copy of the completed application for submission to the assistance program. (Figure 5, par. 55). At the time of the applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify the method of Indicare and Pritchard in combination with the teaching of Hickey, to have the user to provide additional information and a completed application, upon determining that the user/applicant is (more) likely to receive the benefit. As suggested by Hickey, one would have been motivated to include

Art Unit: 3626

this feature to help the applicant find assistance without having to present him/her with an excessive number of questions upfront (par. 55)

[claims 2-6] Indicare gathers information regarding the patient's age and medical condition; income and financial resources. (page 15, Questionnaire) The patient information is compared to well-established criteria (e.g. agency criteria) (page 17—Pharmaceutical company programs)

[claims 9-10] Indicare discloses a system/ method wherein additional patient information includes a discharge diagnosis (page 17-questionnaire). Indicare further discloses providing prompts to assist in the completion of an application (page 12 “patient data” and “physician data” section on screen shots)

[claim 11] Indicare discloses determining whether the patient is covered by an assistance program. (page 17 questionnaire—asks patient if they have health insurance)

[claim 12] Indicare discloses determining whether the patient is previously in the system with a claim/application for assistance. (page 13—allows users to start with old claim/application information.

6. Claims 13, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Indicare™- On-line Patient Assistance Program Website Users Manual.” (referred to hereinafter as Indicare) in view of Pritchard (US 4,491,725) .

[claim 13] Indicare discloses a method for accepting a referral for a patient, comprising the steps of:

- receiving a patient referral, the patient referral including initial patient information, (physician letters requesting assistance from the pharmaceutical company (i.e. donator) on behalf of the patient. (pages 3,5-6)
- determining whether to accept the patient referral by:
 - o comparing the initial patient information to a well-established criteria associated with an assistance program; (pg. 12, step 7)
 - o if the comparison indicates that the initial patient information satisfies the well-established criteria, then accepting the patient referral; (page17— indicates whether pharmaceutical company is likely to decline/ require additional information.)
 - o if the patient referral is accepted, then obtaining additional patient information; (page17—indicates whether pharmaceutical company is likely to decline/ require additional information.)

Claim 13 has been amended to further recite the assistance program is for “Medicaid” and

- o comparing the initial patient information and the additional patient information to eligibility requirements for the assistance program; and

- if the comparison indicates it is likely that benefits can be obtained under the Medicaid assistance program, then providing an application for the Medicaid assistance program. (page 14-15,17—i.e. acceptance or denial of a claim)

Indicare discloses receiving patient information for a benefit assistance program, but does not expressly disclose comparing information and eligibility requirements for the Medicare Program.

Pritchard discloses a method further performing comparisons and assessing benefit eligibility for Medicare and Medicaid. (col. 4, lines 30-42; 65-col. 5, line 3; col. 7, lines 7-63). Pritchard also discloses that application/claim forms are provided to claim the benefits. (col. 7, lines 37-50) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Indicare with the teaching of Pritchard to provide an indication of whether or not benefits will be received. As suggested by Pritchard, one would have been motivated to include these features to minimize the hardship to patients (e.g. low income and elderly patients) by reducing the likelihood that they will have to pay full service fees, while not shifting the burden to healthcare providers. (col. 2, lines 15-25)

[claim 17] Indicare further discloses providing prompts to assist in the completion of an application (page 12 “patient data” and “physician data” section on screen shots)

[claim 18] Indicare discloses automatically completing a section of the application using the initial patient information. (pages 13-14)

Art Unit: 3626

[claims 19-21] Indicare discloses a method wherein the patient referral is received and accepted by a pharmaceutical company (i.e. an entity independent of the medical provider providing patient treatment)(page 17). Indicare further discloses that medical providers still cover some of the cost to accepted participants (page 3, last paragraph). Indicare further discloses submitting and monitoring the application to the assistance program (page 14-15,17—i.e. acceptance or denial of a claim)

7. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Indicare™- On-line Patient Assistance Program Website Users Manual” ,Pritchard, and Hickey (USUS 2002/0107849A1) in view of DeTore et al (USPN 4,975,840).

[claims 7-8] Indicare discloses the method/system of claim 1 as explained in the rejection of claim 1, but does not expressly disclose examining probability models. However, DeTore discloses that it is well known in the insurance arts to examine probability models for policy (e.g. assistance programs) acceptance. (col. 18, lines 23-32) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system and method of Indicare with the teaching DeTore to compare patient information to probability models. As suggested by DeTore, one would have been motivated to include this feature to assist the program in avoiding excessive financial losses (col. 18, lines 23-63)

Art Unit: 3626

8. Claims 14-16, and 22- 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Indicare™- On-line Patient Assistance Program Website Users Manual” and Pritchard in view of DeTore et al (USPN 4,975,840).

[claims 14-16] Indicare discloses the method/system of claim 13 as explained in the rejection of claim 13, but does not expressly disclose examining probability models.

However, DeTore discloses that it is well known in the insurance arts to examine probability models for policy (e.g. assistance programs) acceptance. (col. 18, lines 23-32) At the time of the applicant’s invention, it would have been obvious to one of ordinary skill in the art to modify the system and method of Indicare with the teaching DeTore to compare patient information to probability models. As suggested by DeTore, one would have been motivated to include this feature to assist the program in avoiding excessive financial losses (col. 18, lines 23-63)

[claim 22,26] Indicare discloses a method for identifying and applying for benefits for a patient comprising the steps of :

- obtaining initial patient information (i.e. application/enrollment forms (page 3, 7-10; 15-16).
- based upon initial patient information, making an initial determination as to whether it is likely that the benefits can be obtained (pg. 12, step 7) by comparing initial patient information to well-established criteria (page 17— Pharmaceutical company programs)

- if the initial determination is that benefits are likely to be obtained, obtaining additional patient information, (page 17—indicates whether pharmaceutical company is likely to decline/ require additional information.)
- providing a second indication that benefits are likely and selecting the identified the assistance program (page 14-15, 17—i.e. acceptance or denial of a claim)

Claim 22 has been amended to recite “making a subsequent determination as to whether it is likely that benefits can be obtained for the patient by comparing the initial patient information and the additional patient information to the first and second assistance program[s] that [are] identified.” Indicare discloses the features of claim as explained above, but does not expressly disclose making a subsequent determination as to whether it is likely that benefits can be obtained for the patient by comparing the initial patient information and the additional patient information to the first and second assistance program[s] that [are] identified.

Pritchard discloses a method further comprising making a subsequent determination as to whether it is likely that benefits can be obtained for the patient by comparing the initial patient information and the additional patient information to the first and second assistance program[s] that [are] identified. (col. 5, lines 40-65; col. 7, line 7-37; col. 8, lines 30-43—reviews secondary and tertiary insurance coverage qualifications, Medicare/Medicaid qualifications.) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Indicare with the teaching of Pritchard to provide an indication of whether or

not benefits will be received. As suggested by Pritchard, one would have been motivated to include these features to minimize the hardship to patients (e.g. low income and elderly patients) by reducing the likelihood that they will have to pay full service fees, while not shifting the burden to healthcare providers. (col. 2, lines 15-25)

Indicare discloses the method/system of claim 22 as explained above, but does not expressly disclose examining probability models. However, DeTore discloses that it is well known in the insurance arts to examine probability models for policy (e.g. assistance programs) acceptance. (col. 18, lines 23-32) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system and method of Indicare and Pritchard in combination with the teaching DeTore to compare patient information to probability models. As suggested by DeTore, one would have been motivated to include this feature to assist the program in avoiding excessive financial losses (col. 18, lines 23-63)

[claim 23] Indicare further discloses providing prompts to assist in the completion of an application (page 12 "patient data" and "physician data" section on screen shots)

[claims 24-25] Indicare gathers information regarding the patient's age and medical condition; income and financial resources. (page 15, Questionnaire). The patient information is compared to well-established criteria (e.g. agency criteria) (page 17—Pharmaceutical company programs)

[claim 27-28] Indicare and Pritchard disclose the method/system of claim 22, but do not expressly disclose examining probability models. However, DeTore discloses that it is well known in the insurance arts to examine probability models for policy (e.g. assistance programs) acceptance. DeTore further discloses that the probability models used are based upon prior experience in obtaining similar coverage (i.e. benefits under the second assistance program) (col. 18, lines 23-32) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system and method of Indicare with the teaching DeTore to compare patient information to probability models. As suggested by DeTore, one would have been motivated to include this feature to assist the program in avoiding excessive financial losses (col. 18, lines 23-63)

9. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Indicare™- On-line Patient Assistance Program Website Users Manual," and Pritchard, and in further view of Admitted Prior Art (in accordance with MPEP 2144.03) [claims 29-30] Indicare and Pritchard disclose the method of claim 13 as explained in the rejection of claim 13, but do not expressly disclose that the Medicaid assistance program is for disability or includes analysis of indigence status. However, it is well known that indigence/income and disability are eligibility criteria for Medicaid. At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to review the elements for applicant. One would have been motivated to include this feature to comply with state and federal standards and regulations.

Applicant has failed to traverse the use of Official Notice in rejection of these claims in the Final Rejection mailed 12/12/07. As such, the noted facts are now considered admitted prior art in accordance with MPEP 2144.03.

Response to Arguments

10. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

The examiner has provided an additional reference and citations to address applicant's arguments regarding the newly added features.

(A) Applicant argues that Indicare fails to disclose several of the features of the applicant's invention.

In response, it is submitted that the current language is quite broad. For example in arguing that the Indicare reference does not disclose "making a determination" the applicant concedes the prior art does determine whether a drug qualifies for reimbursement. (page 12). This is in fact a benefit for which certain individuals may qualify, while others may be denied. The current claim language recites and establishes no parameters for qualification or the "determination process." (See the 101 rejection.) As such the Examiner has given the claims the broadest reasonable interpretation and applied art accordingly.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

Art Unit: 3626

(i.e., the computer application creates a record of whom the patient is; the computer generates a completed application) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Klesse (US 5583760A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626